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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,891	03/17/2004	Christoph Seidel	NY-HUBR 1067.4 DIV	5294

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,891	SEIDEL ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27-30* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed December 7, 2006 in response to the Office Action of September 20, 2006 is acknowledged and entered. Claims 27-30 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 27 and 28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is maintained.

Applicant amended the claims recite "determining" instead of "to determine". However this amendment does not overcome the present rejection because the claims still lack a measurement step or positive process steps to carry out the claimed methods. There is lack of recitation of a measurement step in which the HCV specific antibody is detected. The present claims recite the method steps with regard to incubating, determining and comparing the results from different time points. However the claims do not recite the measurement steps in which the HCV specific antibody is detected. Lacking enough steps to define a method for determining seroconversion, claims 27 and 28 are incomplete and merely define an immunoassay as presently recited. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 27-30 under 35 U.S.C. 103(a) as being unpatentable over Vallari et al. in view of Takei et al. **is maintained**.

Applicant's arguments have been fully considered but are not persuasive. Applicants argue that although Vallari did test for the presence of the anti- NS3 antibodies, Vallari does not suggest that the determination of seroconversion could be achieved by using reducing conditions in an NS3 based assay. Applicants also argue that while Takei teaches determining NS3 specific antibodies in a reducing buffer, Tekei does not suggest that his assay could be adopted for determining seroconversion. Examiner points out that determining seroconversion of the present invention comprises incubating the human sample (the sample comprising antibodies) with NS3 protein of HCV under reducing conditions. Takei expressly teach incubating the human sample with NS3 protein of HCV under reducing conditions (see claims 1-10 and page 5). Takei also teach that using reducing conditions in detection of anti-NS3 antibodies, that is using the same agents as those identified in the current specification (see [0027]) such as DDT or DTE, results in increased sensitivity of antibody detection for the following reasons: A thiol group in cysteine of the HCV NS3 protein is subjected to natural oxidation and change in disulphide bond, which results in decreased sensitivity of the measurement assay. Based on that knowledge Takei discovered that the addition of a reducing agent, in particular a thiol-protecting agent, to the

HCV measurement system results in increased sensitivity of the HCV antibody measurement (see pages 6 and 7). Thus Takei teaches and suggests that using reducing conditions while detecting anti-NS3 antibodies results in increased sensitivity of anti-NS3 antibody measurement. Based on the teaching of Takei, one would have been motivated to detect anti-NS3 antibodies under reducing conditions in Vallari's method of detecting HCV seroconversion. Thus because the cited references in combination teach and suggest the present invention the rejection is maintained.

Applicants further refer to the Declaration of Ursula Wienhues –Thelen filed December 7, 2006. In order to advance the prosecution of the present Application Examiner considered the unsigned Declaration of Ursula Wienhues –Thelen. If the Declaration had been signed, the Declaration would not have overcome the present rejection for the following reasons.

In points 1 and 2 of the Declaration, Dr. Wienhues -Thelen identifies herself as a co-inventor of the claimed subject matter.

In point 3, Dr. Wienhues -Thelen states that the reference by Takei JP06074956 is irrelevant to the invention in the present Application.

In point 4-6 Dr. Wienhues -Thelen states that JP06074956 reference discusses how HCV antibodies are determined "which is not the same thing as determining early seroconversion in a sample" for the number of reasons. In response the Office points out that JP06074956 reference was cited in the present rejection, for the purpose of showing that the benefits of using reducing conditions in detection of anti-NS3 antibodies have been known in the art at the time the current invention was made as evidenced by teaching of Takei (see discussion above). Vallari teaches determination of seroconversion in a human infected with HCV involving incubating human

samples with NS3 protein. Thus the combination of the references, and not individual references render the claimed invention obvious as discussed above.

In point 7, Dr. Wienhues -Thelen states that neither the impact of reducing buffer conditions on the presentation of epitopes of NS3 recognized by early seroconversion antibodies nor the effects of reducing buffer conditions on the binding affinity of epitopes to early seroconversion antibodies are suggested by JP06074956. Examiner respectfully disagrees. It is understood that the term "seroconversion" refers to a change of antibody specificity to NS3 protein as compared to measuring the said specificity at two different time points. The fact that Takei (JP06074956) does not expressly teach seroconversion is irrelevant, because Takei teach the impact of reducing buffer conditions on the presentation of epitopes of NS3 recognized by anti-NS3 antibodies. Because Vallari teaches seroconversion, Vallari teaches comparing the antibody specificity to NS3 protein as measured at different time points. It is also noted that the current claims do not recite *early* seroconversion.

In point 8, Dr. Wienhues -Thelen cites references supporting the statement of the present Declaration.

In point 9, Dr. Wienhues –Thelen presents statements with regard to a reference by Beach, which is not cited in the current rejection. Therefore Examiner makes no comments on statements in point 8.

In point 10, Dr. Wienhues –Thelen states that in Vallari's reference the response to the core antigen and not NS3 antigen was most frequent. However, because Vallari measured the response to the NS3 antigen in order to determine seroconversion, the fact that the response to the core antigen was more frequent is irrelevant. Dr. Wienhues –Thelen states that Vallari does

not suggest using reducing buffers in assay for NS3 antigens to determine early seroconversion. Examiner points out that a suggestion of using reducing buffers in assay for NS3 antigens can be found in the JP06074956 reference.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB
Agnieszka Boesen, Ph.D.
6/11/07

/Stacy B. Chen/ 6-11-2007
Primary Examiner, TC1600